## REMARKS

This paper is responsive to the Office Action dated January 29, 2004, which is the first action on the merits of the application.

Claims 23-48 were previously pending in the application. Claims 23-33 and 47-48 are withdrawn. Upon entry of this amendment, claim 48 is cancelled without prejudice. Claims 34-46 are currently under examination

Reconsideration and allowance of the application is respectfully requested.

Interview:

The undersigned thanks Examiner Anne-Marie Falk, Ph.D., for the helpful interview held at the Patent Office on March 11, 2004. The Examiner made suggestions for addressing the § 112 ¶ 2 issues, which have been incorporated into this response. The issue under § 112 ¶ 1 will be considered in conjunction with USSN 09/859,351, in which a similar issue was raised.

Amendments

The internet URLs in the specification have been deleted, as requested. The reader may readily obtain the internet address for GenBank and "Gene Chips (DNA Microarrays)" using an internet search engine.

Reference to "TNF-β superfamily antagonist" in the legend of Figure 4 has been corrected to "TGF-β superfamily antagonist", for the convenience with the reader, to make it consistent with the claimed invention and the working example (Example 5, page 33 ff.: see Table 3, Group 5).

No new matter is added to the disclosure as a result of the amendments to the claims. The amendments are supported by the claims as previously presented and throughout the specification. Recitation of "progeny" in claims 36-38 has been removed as unnecessary. The skilled reader will appreciate that the steps indicated in these claims may be part of a derivation protocol involving several steps (e.g., an optional predifferentiation step before culturing with particular agents). No new limitations are added. Accordingly, coverage is maintained for all equivalents of the claimed subject matter for which applicant was previously entitled.

Rejections under 35 USC § 112 ¶ 1

Claims 34-46 stand rejected under the written description requirement of § 112 ¶ 1 as containing new matter not described in the specification. Claims 3446 also stand rejected under the enablement requirement of § 112 ¶ 1, on the basis that the specification does not show how to use the two cell populations together. The Office Action implies that the two cell populations are being claimed as a kit or some other product combination in which the cells are actually made to interact or are distributed together for commercial purposes.

Applicant respectfully disagrees. The claimed product is actually a "system" for producing differentiated cells having characteristics of cells in the neural cell lineage. Certain embodiments of the invention are described as a "system" *inter alia* at the outset of the Summary (page 3, lines 3-4), and the outset of the Detailed Description (page 7, lines 1-4). The context of these terms in the application as a whole makes it clear that the "system" is a strategy and set of reagents that can be used to generate neural lineage cells from hES cells. As embodied in claim 35, the system has two essential components: the original hES cell line, and the neural cells derived from them, identifiable by enrichment for characteristic neural cell markers.

Since this is a *product* claim, there is no implied activity for use of the cells together. The claim is satisfied by possession of the two cell populations by the person practicing or using the invention at any time for any purpose. If the skilled user wishes to derive neural cells from hES cells according to the description, they will have possession of the hES cell line, and then they will have possession of the neural cells subsequent to the derivation. In keeping with usual practice in the field, the user will keep a reserve of undifferentiated hES cells while doing the derivation. This means that after the derivation is complete, they will have possession of both cell populations at the same time. While the user may wish to package or distribute the cells together, the claims do not require that this be done.

The following comments parallel remarks made in the prosecution of USSN 09/859,351, in which a similar issue was raised.

The proper inquiry under the description requirement of § 112 ¶ 1 entails taking whatever is presently claimed in the application, and then determining from the specification whether the inventors had possession of it at the time the application was originally filed.

> The written description requirement and its corollary, the new matter prohibition of 35 USC § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. *TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 60 USPQ2d 1017 (Fed. Cir. 2001).
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> The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.* *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991).

The present wording of the claims closely follow the wording used in the application as filed. Even so, exact copying of language from the specification to the claims is not required under U.S. patent law. The nature of the patenting process is a dialog with the Office for the purpose of providing applicants with protection for their commercial interest, while complying with the statutory requirements. In the course of prosecution, applicant is allowed substantial latitude in the wording claims, as long as the claims cover aspects of the invention that were in possession of the inventors at the time of filing.

> Mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible. *In re Anderson*, 176 USPQ 331 (CCPA 1973); MPEP § 2163.07(I).
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> In order to satisfy the written description requirement, the disclosure as originally filed need not provide in *haec verba* support for the claimed subject matter at issue. . . . The requirement is met if 'the disclosure of the application relied upon reasonably conveys to the artisan that the inventor has possession at that time of the later claimed subject matter.' *Lampi Corp. v. American Power Products, Inc.*, 56 USPQ2d 1445 (Fed. Cir. 2000).

In fact, a structure or process not explicitly described can meet the clear conveyance standard of § 112 ¶[ 1 simply by being *inherent* in what is described.

> The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. *Union Oil Co. of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227 (Fed. Cir. 2000), citing *In re Gostelt*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) and *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).
>
> Patent entitlement is based on scientific skill and diligence and not on the ability to manipulate English synonyms. . . . Legal equivalence, or inherency, may be established either by the direct meaning of the language or by inferences drawn from the terms of the initial disclosure. *Standard Oil Co. v. Montedison, S.p.A.* 206 USPQ 676 (D. Del. 1980), *aff'd*, 212 USPQ 327 (3rd Cir. 1981), *cert. denied*, 456 U.S. 915 (1982).

Applying the legal standard founded in the case law to the invention claimed in this application, it is clear that claims 34-46 (both as previously presented, and as amended) meet the description requirements of § 112 ¶ 1.

Specifically, the inventors had possession of the first cell population (the undifferentiated hES cell population) as illustrated in Example 1, page 25 ff.; and the second cell population (the neural lineage cells), as illustrated in Examples 2 (page 27 ff.) and Example 5 (page 33 ff.). Progression of hES cell lines to differentiated cells is illustrated on page 34, line 1 ff., and in Table 4. Cultures of hES cells were differentiated into late-stage neural cells that were positive for βtubulinIII, MAP-2, and tyrosine hydroxylase. Clearly, the inventors had possession of both of the cell populations as part of the "system" embodied in claims 34-46.

Accompanying this Amendment is a Declaration under 37 CFR § 1.132 by Scott Thies, an expert who is skilled in the art of cell biology. As Dr. Thies explains, the application describes a system for making neural lineage cells from primate pluripotent stem (pPS) cells. Dr. Thies indicates that someone making neural cells using the system of the invention would have possession of the undifferentiated pPS cells, and possession of the cells bearing the neural markers, as the cells go through the differentiation process. Dr. Thies also explains that it is usual in practicing the invention to keep a population of pPS cells in the undifferentiated state while generating the neural cells, in order to provide an expandable reserve from which additional neural cells can be generated.

With respect to the enablement rejection, the Office Action infers that the two populations "are intended to be used together somehow." To the contrary: the claim recites only the two cell populations, and is satisfied if in the possession of the user for *any* worthwhile purpose — including but not limited to the derivation of the second cell population from the first.

Product claims need only be enabled for *one* of the possible uses of the invention in order to comply with the requirements of § 112 ¶ 1.

> Utility of the application is shown when the properly claimed invention meets at least one stated objective. A claimed invention need not accomplish all objectives stated in the specification. When a properly claimed invention meets at least one stated objective, utility . . . is clearly shown. *Raytheon Company v. Roper Corporation*, 220 USPQ 592, 598 (Fed. Cir. 1983), citing Standard Oil Co. (Indiana) v. Montedison, S.P.A., 212 USPQ 327,344 (3rd Cir. 1981) and other authorities.

The two cell populations are enabled by the specification as a system for making pPS derived neural cell populations. Dr. Thies explains in his Declaration that someone using the methods provided in the disclosure would be able to make an ongoing supply of pPS derived neural cells. He indicates that the cells obtained would be suitable for a number of different uses described in the specification, such as the preparation of pharmaceutical compositions, and for use in drug screening.

A lengthy discussion of drug screening using the neural cells of this invention is described in the section beginning on page 21, line 26 ff. Figure 5 provides a working example of showing the response of certain neural cells of this invention to various putative neurotransmitters. The application both describes and enables the use of hES derived neural cells for screening putative neurotransmitters and other agents for efficacy or neurotoxicity. Undifferentiated hES cells are enabled for the making of hES derived neurons, and are therefore useful for drug screening after differentiation.

Applicant disagrees with the indication in the Office Action that there are significant obstacles to using stem cells for therapy. The specification describes not only the making of pharmaceutical compositions containing neural cells, but also the preclinical testing of pPS derived neural cells in established animal models. Still, the utility of the claimed cell populations is already satisfied by the drug screening uses already referred to.

In summary, the skilled reader will understand from reading the disclosure as filed that the inventors had possession of the claimed system, in the form of the two cell populations used and made during the course of the differentiation protocol. By following the differentiation protocol as exemplified or otherwise described in the application, the skilled reader may readily implement the system to their own advantage. Accordingly, the claimed invention complies with the description and enablement requirements of 35 USC § 112 ¶ 1.

Withdrawal of this rejection is respectfully requested.

Rejections under 35 USC § 112 ¶ 2:

The claims have been amended in a manner that is believed to obviate all the issues raised in the Office Action under § 112 ¶ 2.

Request for Rejoinder:

Claim 47 is a method of use claim. It has been amended to depends from and incorporate the limitations of product claim 34. Claim 48 has been cancelled.

Applicant hereby requests that claim 47 be rejoined into the elected group, upon determination that the product claims are patentable, in accordance with MPEP § 821.04.

Request for Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

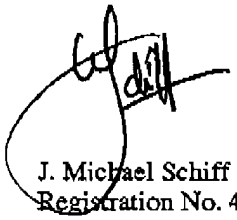
PATENT
09/888,309
Docket 090/002

Fees Due

No fee is required with respect to the amendments to the claims. Enclosed with this Amendment is authorization to charge the Deposit Account for the extension of time.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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May 27, 2004